

**We claim:**

**1. A human milk fortifier composition comprising:**

**(a) protein, lipid, carbohydrate, or combinations thereof; and**

**(b) an iron-containing material containing**

**(i) soluble unbound iron, insoluble iron, or combinations thereof, and**

**(ii) from about 3 mg to about 30 mg soluble iron per 100 g of human milk**

**fortifier solids in the composition,**

**wherein the composition is a human milk fortifier.**

2. The composition of Claim 1 wherein the composition has a total iron content of from about 10 mg to about 110 mg per 100 g of human milk fortifier solids, and wherein from about 10% to 100% by weight of the total iron in the composition is insoluble iron, soluble bound iron, or combinations thereof.

3. The composition of Claim 2 wherein from about 50% to about 95% by weight of the total iron is insoluble iron, soluble bound iron, or combinations thereof.

4. The composition of Claim 1 wherein the composition has a total iron content of from about 20 mg to about 50 mg per 100 g of human milk fortifier solids.

5. The composition of Claim 1 wherein the composition comprises from about 5 mg to about 25 mg soluble iron per 100 g of human milk fortifier solids.

6. The composition of Claim 1 wherein the composition is substantially free of ferrous sulfate, ferric sulfate, and combinations thereof.

7. The composition of Claim 1 wherein the composition comprises one or more iron-containing materials selected from the group consisting of ferrous fumarate, ferrous succinate, ferric saccharate, ferric glycerophosphate, ferrous citrate, ferrous tartrate, ferric pyrophosphate, and ferric orthophosphate.

8. The composition of Claim 1 wherein the composition the iron-containing material comprises ferrous fumarate.

9. The composition of Claim 1 wherein the composition comprises, per 100 g of fortifier solids, from about 15 g to about 75 g of carbohydrate, from about 1 to about 30 g of lipid, and from about 24 g to about 55 g of protein.
10. The composition of Claim 1 wherein the composition comprises, per 100 g of fortifier solids, from about 38 g to about 70 g of carbohydrate, from about 5 g to about 20 g of lipid, and from about 25 g to 42 g of protein.
11. The composition of Claim 1 wherein the composition is in powder form.
12. The composition of Claim 1 wherein the composition is in liquid form.
13. The composition of Claim 12 wherein the liquid composition comprises at least about 20% by weight of fortifier solids and less than about 80% by weight of water.
14. The composition of Claim 12 wherein the liquid composition comprises from about 20% to about 40% fortifier solids and less than about 80% by weight of water.
15. The composition of Claim 12 wherein the liquid composition is a liquid concentrate for use in combination with human milk in a volume/volume ratio of the liquid concentrate to the human milk of from about 1:2 to about 1:10
16. The composition of Claim 1 wherein the composition further comprises an iron availability agent.
17. The composition of Claim 16 wherein the iron availability agent reduces the concentration of soluble unbound iron in the composition by at least about 10% by weight.
18. The composition of Claim 16 wherein the iron availability agent reduces the concentration of soluble unbound iron by at least about 50% by weight.
19. The composition of Claim 16 wherein the iron availability agent comprises up to about 10 g of phosphate ions per 100 g of fortifier solids.

20. The composition of Claim 19 wherein the phosphate ion is provided by  $\text{NaH}_2\text{PO}_4$ ,  $\text{Na}_2\text{HPO}_4$ ,  $\text{KH}_2\text{PO}_4$ ,  $\text{K}_2\text{HPO}_4$ ,  $\text{H}_3\text{PO}_4$ , Ca glycerophosphate,  $\text{Ca}(\text{H}_2\text{PO}_4)_2$ ,  $\text{CaHPO}_4$ ,  $\text{Ca}_3(\text{PO}_4)_2$ ,  $\text{Ca}_2\text{P}_2\text{O}_7$ ,  $\text{Mg}(\text{H}_2\text{PO}_4)_2$ ,  $\text{MgHPO}_4$ ,  $\text{Mg}_3(\text{PO}_4)_2$ ,  $\text{Mg}_2(\text{P}_2\text{O}_7)$ , or combinations thereof.

21. The composition of Claim 1 further comprising at least about 0.1 g of lactoferrin per mg of iron in the composition.

22. A human milk fortifier composition comprising:

(a) protein, lipid, carbohydrate, or combinations thereof; and

(b) an iron-containing material comprising one or more of ferrous fumarate, ferrous succinate, ferric saccharate, ferric glycerophosphate, ferrous citrate, ferrous tartrate, ferric pyrophosphate, or ferric orthophosphate;

wherein the composition is a human milk fortifier.

23. The composition of Claim 22 wherein the composition has a total iron content of from about 10 mg to about 110 mg per 100 g of human milk fortifier solids, and wherein from about 10% to 100% by weight of the total iron in the composition is insoluble iron, soluble bound iron, or combinations thereof.

24. The composition of Claim 23 wherein from about 50% to about 95% by weight of the total iron is insoluble iron, soluble bound iron, or combinations thereof.

25. The composition of Claim 23 wherein the composition has a total iron content of from about 20 mg to about 50 mg per 100 g of human milk fortifier solids.

26. The composition of Claim 22 wherein the iron-containing material comprises ferrous fumarate.

27. The composition of Claim 22 wherein the composition comprises, per 100 g of fortifier solids, from about 15 g to about 75 g of carbohydrate, from about 1 to about 30 g of lipid, and from about 24 g to about 55 g of protein.

28. The composition of Claim 22 wherein the composition comprises, per 100 g of fortifier solids, from about 38 g to about 70 g of carbohydrate, from about 5 g to about 20 g of lipid, and from about 25 g to 42 g of protein.
29. The composition of Claim 22 wherein the composition is in powder form.
30. The composition of Claim 22 wherein the composition is in liquid form.
31. The composition of Claim 30 wherein the liquid composition comprises at least about 20% by weight of fortifier solids and less than about 80% by weight of water.
32. The composition of Claim 30 wherein the liquid composition comprises from about 20% to about 40% fortifier solids and less than about 80% by weight of water.
33. The composition of Claim 30 wherein the liquid composition is a liquid concentrate for use in combination with human milk in a volume/volume ratio of the liquid concentrate to the human milk of from about 1:2 to about 1:10
- 34. A human milk fortifier composition comprising:**  
**(a) protein, lipid, carbohydrate, or combinations thereof;**  
**(b) from about 15 mg to about 110 mg of iron per 100 g of human milk fortifier solids; and**  
**(c) an iron availability agent;**  
**wherein the composition is a human milk fortifier.**
35. The composition of Claim 34 wherein the composition has a total iron content of from about 20 mg to about 50 mg per 100 g of human milk fortifier solids.
36. The composition of Claim 34 wherein the composition comprises soluble unbound iron, and wherein the iron availability agent reduces the soluble unbound iron concentration by at least about 10% by weight.
37. The composition of Claim 36 wherein the iron availability agent reduces the concentration of soluble unbound iron by at least about 50% by weight.

38. The composition of Claim 34 wherein the iron availability agent comprises up to about 10 g of phosphate ions per 100 g of fortifier solids.
39. The composition of Claim 34 wherein the phosphate ion is provided by  $\text{NaH}_2\text{PO}_4$ ,  $\text{Na}_2\text{HPO}_4$ ,  $\text{KH}_2\text{PO}_4$ ,  $\text{K}_2\text{HPO}_4$ ,  $\text{H}_3\text{PO}_4$ , Ca glycerophosphate,  $\text{Ca}(\text{H}_2\text{PO}_4)_2$ ,  $\text{CaHPO}_4$ ,  $\text{Ca}_3(\text{PO}_4)_2$ ,  $\text{Ca}_2\text{P}_2\text{O}_7$ ,  $\text{Mg}(\text{H}_2\text{PO}_4)_2$ ,  $\text{MgHPO}_4$ ,  $\text{Mg}_3(\text{PO}_4)_2$ ,  $\text{Mg}_2(\text{P}_2\text{O}_7)$ , or combinations thereof.
40. The composition of Claim 34 wherein from about 10% to 100% by weight of the total iron in the composition is insoluble iron, soluble bound iron, or combinations thereof.
41. The composition of Claim 34 wherein from about 50% to about 95% by weight of the total iron is insoluble iron, soluble bound iron, or combinations thereof.
42. The composition of Claim 34 wherein the composition is substantially free of ferrous sulfate, ferric sulfate, and combinations thereof.
43. The composition of Claim 34 wherein the composition comprises, per 100 g of fortifier solids, from about 15 g to about 75 g of carbohydrate, from about 1 to about 30 g of lipid, and from about 24 g to about 55 g of protein.
44. The composition of Claim 34 wherein the composition comprises, per 100 g of fortifier solids, from about 38 g to about 70 g of carbohydrate, from about 5 g to about 20 g of lipid, and from about 25 g to 42 g of protein.
45. The composition of Claim 34 wherein the composition is in powder form.
46. The composition of Claim 34 wherein the composition is in liquid form.
47. The composition of Claim 46 wherein the liquid composition comprises at least about 20% by weight of fortifier solids and less than about 80% by weight of water.
48. The composition of Claim 46 wherein the liquid composition comprises from about 20% to about 40% fortifier solids and less than about 80% by weight of water.

49. The composition of Claim 46 wherein the liquid composition is a liquid concentrate for use in combination with human milk in a volume/volume ratio of the liquid concentrate to the human milk of from about 1:2 to about 1:10

50. The composition of Claim 34 further comprising at least about 0.1 g of lactoferrin per mg of iron in the composition.

**51. A human milk fortifier composition comprising:**

**(a) protein, lipid, carbohydrate, or combinations thereof;**

**(b) an iron-containing material; and**

**(c) at least about 0.1 g lactoferrin per mg of iron in the composition;**

**wherein the composition is a human milk fortifier.**

52. The composition of Claim 51 wherein the composition comprises from about 0.7 g to about 3 g lactoferrin per mg of iron in the composition.

53. The composition of Claim 51 wherein the composition has a total iron content of from about 10 mg to about 110 mg per 100 g of human milk fortifier solids, and wherein from about 10% to 100% by weight of the total iron in the composition is insoluble iron, soluble bound iron, or combinations thereof.

54. The composition of Claim 51 wherein from about 50% to about 95% by weight of the total iron is insoluble iron, soluble bound iron, or combinations thereof.

55. The composition of Claim 51 wherein the composition has a total iron content of from about 20 mg to about 50 mg per 100 g of human milk fortifier solids.

56. The composition of Claim 51 wherein the composition comprises, per 100 g of fortifier solids, from about 15 g to about 75 g of carbohydrate, from about 1 to about 30 g of lipid, and from about 24 g to about 55 g of protein.

57. The composition of Claim 51 wherein the composition comprises, per 100 g of fortifier solids, from about 38 g to about 70 g of carbohydrate, from about 5 g to about 20 g of lipid, and from about 25 g to 42 g of protein.

58. The composition of Claim 51 wherein the composition is in powder form.
59. The composition of Claim 51 wherein the composition is in liquid form.
60. The composition of Claim 59 wherein the liquid composition comprises at least about 20% by weight of fortifier solids and less than about 80% by weight of water.
61. The composition of Claim 59 wherein the liquid composition comprises from about 20% to about 40% fortifier solids and less than about 80% by weight of water.
62. The composition of Claim 59 wherein the liquid composition is a liquid concentrate for use in combination with human milk in a volume/volume ratio of the liquid concentrate to the human milk of from about 1:2 to about 1:10
- 63. A human milk fortifier composition comprising:**  
    **(a) protein, lipid, carbohydrate, or combinations thereof; and**  
    **(b) from about 15 mg to about 110 mg of iron per 100 g of fortifier solids, wherein from about 30% to 100% by weight of the iron in the composition is insoluble iron, soluble bound iron, or combinations thereof;**  
**wherein the composition is a human milk fortifier.**
64. The composition of Claim 63 wherein from about 50% to about 95% by weight of the iron is insoluble iron, soluble bound iron, or combinations thereof.
65. The composition of Claim 63 wherein the composition comprises from about 20 mg to about 50 mg of iron per 100 g of human milk fortifier solids.
66. The composition of Claim 63 wherein the composition is substantially free of ferrous sulfate, ferric sulfate, and combinations thereof.
67. The composition of Claim 63 wherein the composition comprises one or more of ferrous fumarate, ferrous succinate, ferric saccharate, ferric glycerophosphate, ferrous citrate, ferrous tartrate, ferric pyrophosphate, or ferric orthophosphate.

68. The composition of Claim 63 wherein the composition comprises ferrous fumarate.
69. The composition of Claim 63 wherein the composition comprises, per 100 g of fortifier solids, from about 15 g to about 75 g of carbohydrate, from about 1 to about 30 g of lipid, and from about 24 g to about 55 g of protein.
70. The composition of Claim 63 wherein the composition comprises, per 100 g of fortifier solids, from about 38 g to about 70 g of carbohydrate, from about 5 g to about 20 g of lipid, and from about 25 g to 42 g of protein.
71. The composition of Claim 63 wherein the composition is in powder form.
72. The composition of Claim 63 wherein the composition is in liquid form.
73. The composition of Claim 72 wherein the liquid composition comprises at least about 20% by weight of fortifier solids and less than about 80% by weight of water.
74. The composition of Claim 72 wherein the liquid composition comprises from about 20% to about 40% fortifier solids and less than about 80% by weight of water.
75. The composition of Claim 72 wherein the liquid composition is a liquid concentrate for use in combination with human milk in a volume/volume ratio of the liquid concentrate to the human milk of from about 1:2 to about 1:10
76. The composition of Claim 63 wherein the composition further comprises an iron availability agent.
77. The composition of Claim 76 wherein the iron availability agent reduces the concentration of soluble unbound iron in the composition by at least about 10% by weight.
78. The composition of Claim 76 wherein the iron availability agent reduces the concentration of soluble unbound iron by at least about 50% by weight.



79. The composition of Claim 76 wherein the iron availability agent comprises up to about 10 gm of phosphate ions per 100 g of fortifier solids.

80. The composition of Claim 79 wherein the phosphate ion is provided by  $\text{NaH}_2\text{PO}_4$ ,  $\text{Na}_2\text{HPO}_4$ ,  $\text{KH}_2\text{PO}_4$ ,  $\text{K}_2\text{HPO}_4$ ,  $\text{H}_3\text{PO}_4$ , Ca glycerophosphate,  $\text{Ca}(\text{H}_2\text{PO}_4)_2$ ,  $\text{CaHPO}_4$ ,  $\text{Ca}_3(\text{PO}_4)_2$ ,  $\text{Ca}_2\text{P}_2\text{O}_7$ ,  $\text{Mg}(\text{H}_2\text{PO}_4)_2$ ,  $\text{MgHPO}_4$ ,  $\text{Mg}_3(\text{PO}_4)_2$ ,  $\text{Mg}_2(\text{P}_2\text{O}_7)$ , or combinations thereof.

81. A human milk fortifier composition comprising:

(a) protein, lipid, carbohydrate, or combinations thereof; and

(b) an iron-containing material wherein from about 30% to about 70% by weight of the iron in the composition is insoluble iron, soluble bound iron, or combinations thereof,

wherein the composition is a human milk fortifier.

82. The composition of Claim 81 wherein the composition has a total iron content of from about 15 mg to about 100 mg per 100 g of human milk fortifier solids.

83. The composition of Claim 81 wherein the composition has a total iron content of from about 20 mg to about 50 mg per 100 g of human milk fortifier solids.

84. The composition of Claim 81 wherein from about 40% to about 60% by weight of the iron in the composition is insoluble iron, soluble bound iron, or combinations thereof.

85. The composition of Claim 81 wherein the composition is substantially free of ferrous sulfate, ferric sulfate, and combinations thereof.

86. The composition of Claim 81 wherein the composition comprises, per 100 g of fortifier solids, from about 15 g to about 75 g of carbohydrate, from about 1 to about 30 g of lipid, and from about 24 g to about 55 g of protein.

87. The composition of Claim 81 wherein the composition comprises, per 100 g of fortifier solids, from about 38 g to about 70 g of carbohydrate, from about 5 g to about 20 g of lipid, and from about 25 g to 42 g of protein.

88. The composition of Claim 81 wherein the composition is in powder form.
89. The composition of Claim 81 wherein the composition is in liquid form.
90. The composition of Claim 89 wherein the liquid composition comprises at least about 20% by weight of fortifier solids and less than about 80% by weight of water.
91. The composition of Claim 89 wherein the liquid composition comprises from about 20% to about 40% fortifier solids and less than about 80% by weight of water.
92. The composition of Claim 89 wherein the liquid composition is a liquid concentrate for use in combination with human milk in a volume/volume ratio of the liquid concentrate to the human milk of from about 1:2 to about 1:10
93. The composition of Claim 81 wherein the composition further comprises an iron availability agent.
94. The composition of Claim 93 wherein the iron availability agent reduces the concentration of soluble unbound iron by at least about 50% by weight.
95. The composition of Claim 93 wherein the iron availability agent comprises up to about 10 gm of phosphate ions per 100 g of fortifier solids.
96. The composition of Claim 95 wherein the phosphate ion is provided by  $\text{NaH}_2\text{PO}_4$ ,  $\text{Na}_2\text{HPO}_4$ ,  $\text{KH}_2\text{PO}_4$ ,  $\text{K}_2\text{HPO}_4$ ,  $\text{H}_3\text{PO}_4$ , Ca glycerophosphate,  $\text{Ca}(\text{H}_2\text{PO}_4)_2$ ,  $\text{CaHPO}_4$ ,  $\text{Ca}_3(\text{PO}_4)_2$ ,  $\text{Ca}_2\text{P}_2\text{O}_7$ ,  $\text{Mg}(\text{H}_2\text{PO}_4)_2$ ,  $\text{MgHPO}_4$ ,  $\text{Mg}_3(\text{PO}_4)_2$ ,  $\text{Mg}_2(\text{P}_2\text{O}_7)$ , or combinations thereof.
97. A human milk fortifier composition comprising:
- (a) protein, lipid, carbohydrate, or combinations thereof; and
  - (b) an iron-containing material wherein from about 10% to 100% by weight of the iron is insoluble iron, soluble bound iron, or combinations thereof, and wherein the composition is substantially free of ferrous sulfate, ferric sulfate, or combinations thereof;
- and wherein the composition is a human milk fortifier.

98. The composition of Claim 97 wherein the composition contains less than about 0.1mg of ferrous sulfate, ferric sulfate, and combinations thereof, per 100 g of fortifier solids.

99. The composition of Claim 97 wherein from about 50% to 95% by weight of the iron in the composition is insoluble iron, soluble bound iron, or combinations thereof.

100. A method of providing nutrition to infants, said method comprising adding the human milk fortifier of Claim 1 to human milk to form a fortified human milk, and then administering the fortified human milk to the infant.

101. A method of providing nutrition to infants, said method comprising adding the human milk fortifier of Claim 22 to human milk to form a fortified human milk, and then administering the fortified human milk to the infant.

102. A method of providing nutrition to infants, said method comprising adding the human milk fortifier of Claim 34 to human milk to form a fortified human milk, and then administering the fortified human milk to the infant.

103. A method of providing nutrition to infants, said method comprising adding the human milk fortifier of Claim 51 to human milk to form a fortified human milk, and then administering the fortified human milk to the infant.

104. A method of providing nutrition to infants, said method comprising adding the human milk fortifier of Claim 63 to human milk to form a fortified human milk, and then administering the fortified human milk to the infant.

105. A method of providing nutrition to infants, said method comprising adding the human milk fortifier of Claim 81 to human milk to form a fortified human milk, and then administering the fortified human milk to the infant.

106. A method of providing nutrition to infants, said method comprising adding the human milk fortifier of Claim 97 to human milk to form a fortified human milk, and then administering the fortified human milk to the infant.

107. A method of providing nutrition to preterm infants, said method comprising adding the human milk fortifier of Claim 1 to human milk to form a fortified human milk, and then administering the fortified human milk to preterm infants.

108. A method of providing nutrition to preterm infants, said method comprising adding the human milk fortifier of Claim 22 to human milk to form a fortified human milk, and then administering the fortified human milk to preterm infants.

109. A method of providing nutrition to preterm infants, said method comprising adding the human milk fortifier of Claim 34 to human milk to form a fortified human milk, and then administering the fortified human milk to preterm infants.

110. A method of providing nutrition to preterm infants, said method comprising adding the human milk fortifier of Claim 51 to human milk to form a fortified human milk, and then administering the fortified human milk to preterm infants.

111. A method of providing nutrition to preterm infants, said method comprising adding the human milk fortifier of Claim 63 to human milk to form a fortified human milk, and then administering the fortified human milk to preterm infants.

112. A method of providing nutrition to preterm infants, said method comprising adding the human milk fortifier of Claim 81 to human milk to form a fortified human milk, and then administering the fortified human milk to preterm infants.

113. A method of providing nutrition to preterm infants, said method comprising adding the human milk fortifier of Claim 97 to human milk to form a fortified human milk, and then administering the fortified human milk to preterm infants.